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| 10/713,244 | 11/13/2003 | Whye-Kei Lye | SETGON.002A | 1163 |

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| EXAMINER |
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ISABELLA, DAVID J

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| ART UNIT | PAPER NUMBER |
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3738

| SHORTENED STATUTORY PERIOD OF RESPONSE | NOTIFICATION DATE | DELIVERY MODE |
|----------------------------------------|-------------------|---------------|
| 3 MONTHS | 03/27/2007 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/27/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/713,244

Applicant(s)

LYE ET AL.

Examiner

DAVID J. ISABELLA

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-7,9,11,12,14,16-21 and 45-54 is/are pending in the application.
- 4a) Of the above claim(s) 46-49 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-7,9,11,12,14,16-19,21,42 and 43 is/are rejected.
- 7) ☒ Claim(s) 20,44,45 and 50-53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Election/Restrictions

Newly submitted claims 46-49 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are drawn to non-elected speices.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, the claims are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

The amendment filed 12/12/2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: applicant's attempt to define the structure as a nanoporous sponge layer according to that as described in Erlebacher is not fully supported by the original specification. If applicant's method employs the same method as Erlebacher and applicant's provides evidence of

such, then incorporation of the features of Erlebacher will be admitted to the specification.

Prior to the last sentence of the paragraph, Applicants have inserted the sentence “In some instances, the nanoporous sponge layer may be characterized morphologically as coalesced clusters or islands interconnected by ligament structures.” No new matter had been added by this amendment, as support for this amendment is also depicted in Figures 2A and 2B. These descriptive terms for the porous sponge layer are consistent with descriptions found in the Erlebacher article on pg. 451, second column, second full paragraph, which states “Central to this description is the the [sic] coalescence of gold adatoms into stable clusters. The spacing between the ‘islands’ in the initial states of dissolution is close to the spacing between ligaments in the final porous structure.”¹ The full citation to the Erlebacher article is provided in paragraph [0014]. Thus, the foregoing

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Fleming [3190749] or Erlebacher [Publication 2001}.

A method of fabricating a metal substrate including providing at least one alloy and removing at least one component of the alloy to form at least one porous layer is

fully disclosed by either of Fleming or Erlebacher. Applicant argues that the prior art fails to specifically disclose the process on an implantable medical device.

The Examiner rejected Claims 1 and 2 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,190,749 to Fleming. According to the Examiner, Fleming discloses a method of fabricating a metal substrate including providing at least one alloy and removing at least one component of the alloy to form at least one porous layer. However, Fleming does not disclose the use of such processes on an implantable medical device, as required by Claim 1. Indeed, the only disclosed functions for the porous structures in Fleming is as “catalysts or as lubricant accommodators” (Fleming, Col. 1, lines 16-21). No medical-related application is disclosed anywhere in the patent. Because Fleming fails to disclose each and every claim limitation of Claim 1, Claim 1 is not anticipated by Fleming.

The method steps as set forth in claim includes the step of providing a substrate (ie. implantable medical device) and selectively removing an alloy component from the substrate. The claim is not specific to any particular “implantable medical device” until dependent claim 4 which further recites the device is a stent. Dependent claim 9 further defines the material composition of the device including gold and silver. Since the prior art teaches forming nanoporosity in an alloyed substrate including the alloys listed in claim 9 by selectively removing at least one alloy subcomponent to form a tortuous porous device that is capable of being used in the body (ie. biocompatible), then the limitations of the claims are fully met by the prior art to either of Fleming or Erlebacher.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,4-7,9,11,12,14,16-18,21 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erlebacher et al [Publication 2001], Fleming [3190749] or Sieradzki et al [4977038] in view of any of Hanson et al [5985307], Racchini [5569198], Summer et al [5980551] and Dang et al [6758859] or alternatively, any of Hanson et al [5985307], Racchini [5569198], Summer et al [5980551] and Dang et al [6758859] in view of any of Erlebacher et al [Publication 2001], Fleming [3190749] or Sieradzki et al [4977038]

Each of Erlebach et al, Fleming and Sieradzki et al teach forming porous metallic substrate by removing certain alloyed portions creating a porous matrix. The use of nanoporous substrate in the medical field as devices used in vitro and in vivo are taught by any of the secondary teachings. To use the porous substrate of the primary references as a medical device, including a stent would have been obvious from the teachings of any one of the secondary references. To fabricate the nanoporous device of any one of the primary references by a dealloying process would have been obvious from the teachings of any of Erlebacher et al, Fleming and Sieradzki et al to provide a non-corrosive surface which would reduce unwanted leachings of metallic ions in vivo.

Claims 4 and 5, see Summer et al or Dang et al.

Claims 6-7,9, see Erlebacher et al.

Claims 11 and 12, see teachings in columns 1 and 2 of Fleming,

Claims 14 and 16, see Erlebacher et al, Fleming or Sieradzki et al.

Claims 17-18, see Summer et al or Dang et al.

Claims 21 and 54, see the primary devices as modified by Fleming or Sieradzki et al supra.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Erlebacher et al [Publication 2001], Fleming [3190749] or Sieradzki et al [4977038] in view of any of Hanson et al [5985307], Racchini [5569198], Summer et al [5980551] and Dang et al [6758859] or alternatively, any of Hanson et al [5985307], Racchini [5569198], Summer et al [5980551] and Dang et al [6758859] in view of any of Erlebacher et al [Publication 2001], Fleming [3190749] or Sieradzki et al [4977038] as applied to claim 1 above, and further in view of MacGregor [4459252].

A vascular prosthesis having a plurality of layers and porosities is taught by MacGregor. Though it is not clear if the primary references disclose the method for forming a metallic substrate having a plurality of porous layers, such concept for providing fluid communication with the surface pores to promote new tissue growth and flow of nutrients is clearly taught by MacGregor.

The porous surface intended to engage blood must have an interconnected network of pores beneath the surface in fluid flow communication with the surface pores to promote the colonization by nucleated cells and subsequent differentiation into other cell types so that the tissue which is formed and grows into the surface is interlocked in the subsurface network rendering the surface non-thrombogenic. The network of pores preferably extends substantially throughout the body of the porous system.

The interstitial pore size may vary widely, generally from about 1 micron up to about 1000 microns, although it may be preferred to use pore sizes below about 20 microns. The porosity also may vary widely, generally from about 8% by volume to the limit of coherence of the porous surface, and usually in the range of about 10 to about 50% by volume.

The porous surface may be provided as part of a composite of a porous coating embodying the surface on a coherent substrate in certain embodiments of the invention, although a wholly porous structure may be used. The thickness of the porous coating may vary from double layers of particles upwards, generally from about 1 to about 10,000 microns, thin layers being preferred in devices having close tolerances.

To provide more than one porous layer to the device of any of the primary references to promote new tissue formation would have been obvious from the teachings of MacGregor.

Allowable Subject Matter

Claims 20,44,45,50-53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

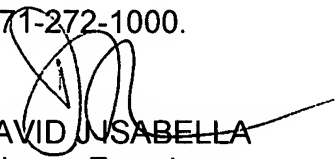
§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DAVID USABELLA
Primary Examiner
Art Unit 3738

DJI
3/12/2007